MEDICAL POLICY STATEMENT
OHIO MARKETPLACE

Policy Name	Policy Number	Date Effective
Inhaled Nitric Oxide	MM-1054	08/01/2021-08/31/2022
Policy Type		

- Malaria

C. Definitions

- Extracorporeal membrane oxygenation (ECMO) - Is temporary support of heart and lung

is the most common clinical problem seen in term, near-term (born at 34 or more weeks of gestation), and pre-term (less than 34 weeks of gestation) infants admitted to neonatal intensive care units. Acute respiratory failure is frequently associated with meconium aspiration syndrome, sepsis, pulmonary hypoplasia, and primary pulmonary hypertension of the newborn.

Management of infants with respiratory failure includes administration of high concentrations of oxygen, hyperventilation, high-frequency ventilation, induction of alkalosis, neuromuscular blockade, antenatal steroids for the prevention of respiratory distress syndrome, use of post-natal steroids for the prevention of chronic lung disease, as well as inhaled nitric oxide (INO) therapy.

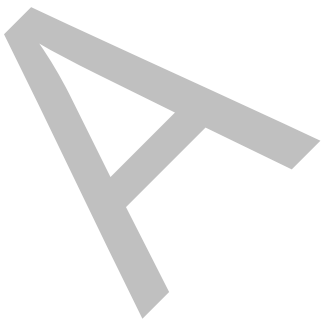
Clinical studies have shown that inhaled nitric oxide is a selective pulmonary vasodilator without significant effects on the systemic circulation. There is scientific evidence that INO therapy improves oxygenation and ventilation, reduces the need for extracorporeal membrane oxygenation (ECMO), and lowers the incidences of chronic lung disease and death among infants with respiratory failure. Moreover, the literature indicates that INO does not appear to increase the incidence of adverse neurodevelopmental, behavioral, or medical sequelae in these high-risk neonates. Infants with congenital diaphragmatic hernia have not shown to benefit from INO therapy. A systemic review of the evidence (Barrington a

Mortality rates in the neonatal intensive care unit (NICU) did not differ for infants treated with INO versus those not treated with INO (RR 0.97 (95 % CI: 0.82 to 1.15)). Broncho-pulmonary dysplasia at 36 weeks for INO and control groups also did not differ (RR 0.93 (0.86, 1.003) for survivors). A small difference was found between INO and control infants in the composite outcome of death or BPD (RR 0.93 (0.87, 0.99)). There was inconsistent evidence about the risk of brain injury from individual RCTs, but meta-analyses showed no difference between INO and control groups. These researchers found no evidence of differences in other short-term risks. There was no evidence to suggest a difference in the incidence of cerebral palsy (RR 1.36 (0.88, 2.10)), neurodevelopmental impairment (RR 0.91 (0.77, 1.12)), or cognitive impairment (RR 0.72 (0.35, 1.45)). Evidence was limited on whether the effect of INO varies by subpopulation or by characteristics of the therapy (timing, dose and duration, mode of delivery, or

In patients with bronchiolitis, the study by González de Dios J (2010), was unable to detect a difference in side effects using intermittent high-dose INO or supportive treatment alone, in infants with moderate bronchiolitis. Tal A, Greenberg D, and colleagues (2018) concluded that this study was unable to detect a difference in side effects using intermittent high-dose INO or supportive treatment alone, in infants with moderate bronchiolitis.

INO has been trialed to enhance antibiotic treatment in infections of patients with Cystic Fibrosis, however, further studies are needed to define dosing, duration and long-term clinical outcomes.

Nitric oxide did not reduce mortality in patients with severe ARDS or mild-moderate ARDS. Acute Respiratory Distress Syndrome (ARDS), is the acute onset of pulmonary edema in the absence of volume overload or depressed left ventricular function. There



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